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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/275,941	03/25/1999	KENICHIRO SATO	Q53788	1435
7590	02/11/2004		EXAMINER	
SUGHRUE MOIN ZINN MACPEAK & SEAS 2100 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20037			OH, TAYLOR V	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/275,941	SATO ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2-3 and 5-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's arguments with respect to claims 1-3 and 5-9 have been considered but are moot in view of the new ground(s) of rejection.

The Status of Claims:

Claims 1-3 and 5-9 are pending.

Claim 1 is rejected.

Claims 2-3 and 5-9 have been objected.

DETAILED ACTION

1. Claims 1-3 and 5-9 are under consideration in this Office Action.

Priority

2. Acknowledgment is made of applicants' claim for foreign priority under 35 U.S.C. 119 (a)-(d).

Drawings

3. There are no drawings filed on 03/25/1999.

Specification

The amendment filed 6/16/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material

Art Unit: 1625

which is not supported by the original disclosure is as follows: for example, the cis/trans geometric isomers of the present invention is different than the original formulas presented in the specification as filed. A close inspection of the original claims and specification do not provide antecedent basis for the proposed changes. New matter can not be introduced into specification at any time during the prosecution, unless there is a supporting description that would support the proposed changes. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The cis/trans geometric isomers of the presently claimed invention are different than the original formulas presented in the claim as filed. A close inspection of the original claims and specification do not provide antecedent basis for the proposed changes. New matter can not be introduced into specification at any time during the

Art Unit: 1625

prosecution, unless there is a supporting description that would support the proposed changes. See 37 CFR 1.75 (d)(1) and 35 USC 132, 112 (first paragraph) in particular.

The proviso statement “ provided that R_3 represent a hydrogen atom when R_1 and R_2 each represent a hydroxyl group” is present in claim 1. A close inspection of the original claims and specification do not provide antecedent basis for the proposed changes. New matter can not be introduced into specification at any time during the prosecution, unless there is a supporting description that would support the proposed changes. See 37 CFR 1.75 (d)(1) and 35 USC 132, 112 (first paragraph) in particular.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Art Unit: 1625

Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlheim et al (*Makromol. Chem.* 193(3), p.779-797) .

Ahlheim et al teaches a structural isomer of the claimed compounds, 7,12-dihydroxy-3-((2-methyl-1-oxo-2-propenyl)oxy)-, 3.alpha, 5. beta, 7.alpha, 12. beta)-Cholan-24-oic acid (see page 781, a structural formula (2-5) on the top of the page).

However, the instant invention differs from the Ahlheim et al reference in the following: R₃ is hydrogen instead of a methyl group.

Concerning R₃ being hydrogen instead of the methyl group, this is related to a homologue of Ahlheim et al's compound. It is well-established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 582 F.2d 638, 199 U.S.P.Q. 137 (C.C.P.A. 1978); In re Hoke, 560 F.2d 436, 195 U.S.P.Q. 148 (C.C.P.A. 1977). Furthermore, if the

Art Unit: 1625

person having an ordinary skill in the art had desired to decrease the lipophilicity of the Ahlheim et al's compound, it would have been obvious to the skillful artisan in the art to have changed R₃ from the methyl group to hydrogen.

Ahlheim et al does teach the structural isomer of the claimed compounds, 7,12-dihydroxy-3-((2-methyl-1-oxo-2-propenyl)oxy)-, 3.alpha, 5. beta, 7.alpha, 12. beta)-Cholan-24-oic acid. Furthermore, in order to decrease the lipophilicity of the Ahlheim et al's compound, it would have been obvious to the skillful artisan in the art to have changed R₃ from the methyl group to hydrogen. In addition, the substitution of methyl for hydrogen on a known compound is not a patentable modification in the absence of unexpected or unobvious results. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to change R₃ to hydrogen so as to decrease the lipophilicity of the Ahlheim et al's compound.

7. Claims 2-3 and 5-9 objected to as being dependent upon the rejected base claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mckane, can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Victor Oh
2/4/04

Margaret Seaman
D. MARGARET SEAMAN
PRIMARY EXAMINER